not the case here. Here, Judge Luckern has examined both the physical and non-physical aspects of the accused tractor and has determined, based upon the evidence presented in the case, that there are non-physical differences *but that they are not material.* The only evidence in the record as to any difference between the 20 additional models of KBT tractors and KTC tractors relates to warning labels, a difference Judge Luckern reasonably determined to be non-physical, and not material.

The Commission's authority to review an initial determination is not wholly discretionary, but rather is defined by the Commission's rules [19 CFR 210.43]. Under the terms of the Commission's rules, the Commission may review an initial determination only if it appears that:

(i) a finding or conclusion of material fact is clearly erroneous;

(ii) a legal conclusion is erroneous, without governing precedent, rule or law, or constitutes an abuse of discretion; or

(iii) the determination is one affecting Commission policy, or if the petition raises a policy matter connected with the initial determination, which the Commission thinks it necessary or appropriate to address.

This initial determination does not fall within the parameters set by the Commission's rules. Our rules do not provide for review simply because one or more Commissioners might have reached a different finding or conclusion. Our rules empower the Administrative Law Judges to make findings and conclusions. Unless their initial determinations raise questions that fit within the criteria set forth in the rules, I believe it inappropriate and impermissible for the Commission to second guess those determinations.

U.S. District Court
Northern District of Georgia

Emory University v. Glaxo Wellcome Inc.

No. 1:96-cv-1868-GET

Decided January 13, 1997, and July 14, 1997

TRADEMARKS AND UNFAIR TRADE PRACTICES

1. Trade secrets — Elements of trade secret (§400.03)

JUDICIAL PRACTICE AND PROCEDURE

Procedure — Pleadings (§410.26)

Patent infringement defendant's statement that plaintiff and counterdefendant obtained and misappropriated "trade secret information regarding BCH-189" chemical compound is vague at best, and plaintiff's motion to compel defendant to provide "detailed factual basis" for trade secret counterclaim in accordance with local rule is therefore granted, since compound in question has many facets, including process for making it, uses in treatment of HIV and other viral infections, and possible side effects, and since there are hundreds, if not thousands, of pages of information that have been published on various aspects of compound.

PATENTS

2. Patentability/Validity — Specification — Written description (§115.1103)

JUDICIAL PRACTICE AND PROCEDURE

Procedure — Summary judgment — Patents (§410.3303)

Issue of whether patent specification adequately describes subject matter claimed, as required by 35 USC 112, is question of fact; in present case, genuine issues of material fact remain as to whether specification of patent in suit contains adequate written description of claimed chemical compound, despite defendants' contention that inventors cannot possibly establish that they were in possession of subject matter of patent at time original application was filed.

3. Patentability/Validity — Obviousness — Relevant prior art — In general (§115.0903.01)

Patent in suit claiming method and compositions for synthesis of chemical compound cannot be held obvious as matter of law over defendant's disclosure, even though, as general proposition, disclosure of racemate or racemic mixture makes prima facie obvious separate enantiomers of that racemate, since, if prior art of record fails to disclose or render obvious method for making claimed compound at time invention was made, it may not be legally concluded that compound itself is in possession of public, and since question remains as to whether enantiomer of compound was in possession of public at time of plaintiff's application, in view affidavit of plaintiff's expert, which states that defendant's disclosure does not suggest pro-

cedure for obtaining enantiomers of claimed compound in separate or enriched form.

Particular patents — Chemical — Nucleoside compounds

5,539,116, Liotta and Choi, method and compositions for the synthesis of BCH-189 and related compounds, infringement defendants' motion for summary judgment of invalidity denied.

Action by Emory University against Glaxo Wellcome Inc. and BioChem Pharma Inc. for patent infringement, in which defendants counterclaim against plaintiff and Raymond Schinazi for misappropriation of trade secret, unfair competition, commercial disparagement, and deceptive trade practices. On plaintiff's motion to compel defendants to provide detailed factual basis for counterclaims in accordance with local rule, and on defendants' motion for summary judgment of patent invalidity. Plaintiff's motion granted.

Robert L. Baechtold, Scott K. Reed, Steven C. Kline, Matthew J. Golden, Leisa M. Smith, Lee B. Shelton, and Gregory B. Sephton, of Fitzpatrick, Cella, Harper & Scinto, New York, N.Y.; Alexander Stephens Clay IV, Thomas C. Harney, and Jeffrey J. Toney, of Kilpatrick Stockton, Atlanta, Ga., for plaintiff and counterdefendant Emory University.

Jesse D. Reingold, Daniel A. Ladow, Gerard Diebner, Albert L. Jacobs, and Brad S. Needleman, of Graham & James, New York; Julius Rodgers Lunsford III and Elizabeth G. Lowry, of Smith, Gambrell & Russell, Atlanta; Mark E. Richardson III and Susan S. Dunn, of Glaxo Wellcome Inc., Research Triangle Park, N.C., for defendant and counterclaimant Glaxo Wellcome Inc.

Russell E. Levine, Peter J. Armenio, Mark A. Pals, Robert G. Krupka, Christian Taylor, and Tobias D. Chun, of Kirkland & Ellis, Chicago, Ill.; James Joseph Thomas II and David Lewis Balser, of Long, Aldridge & Norman, Atlanta; William J. McCabe and James F. Haley, of Fish & Neave, New York; Morton Phillip Levine, of Levine & Block, Atlanta; Sandra A. Bresnick and Pamela A. Huelster, of Kirkland & Ellis, New York, for defendant and counterclaimant BioChem Pharma Inc.

Marlan B. Wilbanks, of Harmon, Smith, Bridges & Wilbanks, Atlanta, for counterdefendant Raymond F. Schinazi.

Tidwell, J.

The above-style matter is presently before the court on plaintiff and counterclaim defendant Emory University's motion to compel [docket no. 27].

Plaintiff and counterclaim defendant Emory University ("Emory") moves the court to compel defendant and counter-claimant BioChem Pharma Inc. ("BioChem") to respond more fully to the mandatory disclosures prescribed by LR 201-4(3), NDGa, particularly mandatory disclosure number 3. Emory contends that BioChem has not provided the "detailed factual basis" required by that rule for Counts II and III of BioChem's counterclaim. Specifically, Emory contends that BioChem has failed to provide any detailed factual basis for BioChem's claim that Emory and Dr. Schinazi misappropriated BioChem's trade secret information. Emory also contends that BioChem has failed to provide a sufficient factual basis for BioChem's unfair competition, commercial disparagement and deceptive trade practices claim. Emory argues that the "detailed factual basis" prescribed by LR 201-4(3), NDGa., must, at a minimum, include "specification and description of each trade secret and each misrepresentation that is a subject of [BioChem's] counterclaim." Therefore, Emory concludes, the court should compel BioChem to provide this information.

BioChem responds that for each count of its counterclaim, including Counts II and III, it has provided information sufficient to answer the questions who, what, when, where, how and why. Thus, BioChem argues, Emory's argument is without merit, and the court should deny Emory's request.

[1] After reviewing BioChem's response to the mandatory disclosures prescribed by LR 201-4(3), the court finds that Emory is entitled to the relief it now seeks. With regard to BioChem's counterclaim based on misappropriation of trade secret information, while BioChem does describe that Emory and Dr. Schinazi obtained and misappropriated "trade secret information regarding BCH-189," this response is vague at best. As Emory points out BCH-189 has many facets: there is a process for making it, a methodology for obtaining its separate enantiomers, a use to treat HIV, a use to treat other viral infections, a toxicity level, possible side effects, a method for formulating it into end-use products, and a marketing and promotion plan. Further, as Emory notes, "hundreds, if not thousands, of pages of information have been published on various

aspects of BCH-189[.]" Therefore, the court GRANTS Emory's motion as it relates to Count II of BioChem's counterclaim and ORDERS BioChem to supplement its response to mandatory disclosure number 3 to include specific information describing the particular trade secret information relating to BCH-189 that BioChem alleges Emory and Dr. Schinazi misappropriated.

Further, with regard to BioChem's misrepresentation counterclaim, the court finds that BioChem's current disclosures are inadequate. Specifically, the court finds that BioChem does not identify who made the alleged misrepresentations, to whom they were made, and when (or on what occasion) they were made. Accordingly, the court further GRANTS Emory's motion as it relates to Count III of BioChem's counterclaim and ORDERS BioChem to supplement its answer to mandatory disclosure number 3 to include information relating to who made the alleged misrepresentations, to whom they were made, and when (or on what occasion) they were made.

SUMMARY

Plaintiff and counterclaim defendant Emory University's motion to compel [docket no. 27] is GRANTED. Defendant and counter-claimant BioChem Pharma Inc. is hereby ORDERED to supplement its response to mandatory disclosure number 3 to include specific information describing the particular trade secret information relating to BCH-189 that BioChem alleges Emory and Dr. Schinazi misappropriated. Defendant and counter-claimant BioChem Pharma Inc. is further ORDERED to supplement is answer to mandatory disclosure number 3 to include information relating to who made the alleged misrepresentations, to whom they were made, and when (or on what occasion) they were made.

SO ORDERED.

July 14, 1997

The above-styled matter is presently before the court on defendant Glaxo Wellcome, Inc.'s motion for summary judgment [docket no. 78].

Background

Plaintiff Emory University ("Emory") brings the instant action against defendants Glaxo Wellcome, Inc. ("Glaxo") and BioChem Pharma Inc. ("BioChem") and alleges that defendants are infringing Emory's rights in United States Patent No. 5,539,116 (the "'116 patent"). Emory contends that the claims of the '116 patent, which issued on July 23, 1996, encompass pharmaceutical products containing "lamivudine" (also known and referred to in the remainder of this order as "3TC"). 3TC is a chemical compound that is used to treat HIV, the virus that causes AIDS.

Defendant Glaxo, both in the United States and in other countries, is the licensee of defendant BioChem's intellectual property rights in 3TC. As BioChem's licensee, Glaxo sells and offers for sale in the United States pharmaceutical products that contain 3TC under the trademark name Epivir®. Emory alleges that by selling and offering for sale products that contain 3TC, defendants are infringing Emory's '116 patent rights.

Defendants have answered and denied all of the complaint's material allegations. Defendants deny that they are, in any way, infringing Emory's '116 patent. In addition, defendants assert that Emory's patent is invalid and should never have issued. Specifically, Glaxo and BioChem contend that the subject matter contained in Emory's '116 patent was not first discovered, publicly disclosed, or patented by Emory, but instead, was invented and discovered by BioChem and/or Glaxo scientists. Glaxo and BioChem also assert several grounds upon which they contend that Emory's '116 patent is invalid and unenforceable, namely: (1) that it lacks a written description of the claimed subject matter; (2) that it improperly contains new matter; (3) that it was anticipated by an earlier filed BioChem patent and published literature; (4) that its subject matter is obvious over an earlier filed BioChem patent and published literature; and (5) that it does not contain subject matter that was first invented by the inventors listed on the patent application.

Defendant Glaxo further argues that Emory's '116 patent should not be enforced on the grounds both that Emory engaged in inequitable conduct before the Patent and Trademark Office during Emory's prosecution of its patent, and that the '116 patent would not have issued had Emory not violated its duty of candor to that office.

Emory counters that its '116 patent is valid in all respects. Emory also contends that it acted at all times fairly and honestly when prosecuting the '116 patent. Specifically, Emory contends that its scientists, rather than Glaxo's and BioChem's, invented 3TC because before Emory filed its patent application neither BioChem nor Glaxo was capable of making that product. Emory further

contends: (1) that every invalidity and unenforceability defense that Glaxo and BioChem raise was considered and withdrawn by the U.S. Patent and Trademark Office when it granted the '116 patent; and (2) that the claims of the '116 patent expressly encompass 3TC.

Finally, defendant BioChem asserts counterclaims against Emory and counterclaim defendant Dr. Raymond Schinazi. Specifically, BioChem contends that Emory and Dr. Schinazi misappropriated trade secret information and engaged in unfair competition. Both Emory and Dr. Schinazi deny these allegations.

Discovery is continuing at this time. Nevertheless, during a mediation conference attended by all of the parties on Friday, May 16, 1997, and based upon representations of Glaxo's counsel that the issue of whether Emory's '116 patent is valid could properly be resolved by summary adjudication, the court authorized Glaxo to brief and support its arguments in a summary judgment motion. On June 5, 1997, defendant Glaxo complied with the court's direction by filing a summary judgment motion that urges the court to declare Emory's '116 patent invalid as a matter of law. BioChem has joined Glaxo's motion for summary judgment and has filed its brief in support of Glaxo's position. Emory has responded, and the matter is now ripe for this court's review.

Standard

Rule 56(c), Fed. R. Civ. P., defines the standard for summary judgment: courts should grant summary judgment when "there is no genuine issue as to any material fact . . . and the moving party is entitled to judgment as a matter of law." Under this rule, the moving party "always bears the initial responsibility of informing the district court of the basis of its motion, and identifying those portions of 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any' which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 324 (1986). Thus, the movant's burden is "discharged by 'showing' — that is, pointing out to the district court — that there is an absence of evidence to support the nonmoving party's case." *Id.* 477 U.S. at 325; *see also United States v. Four Parcels of Real Property*, 941 F.2d 1428, 1437 (11th Cir. 1991).

Once the movant has met this burden, the burden on summary judgment shifts to the nonmoving party who must establish that there is a genuine material issue of fact remaining for trial. *Celotex*, 477 U.S. at 325. The nonmoving party must go beyond the pleadings and submit evidence in the form of affidavits, depositions, admissions and the like, to demonstrate that a genuine issue of material fact exists. *Id.* To survive a motion for summary judgment, nonmoving parties "need only present evidence from which a jury might return a verdict in [their] favor." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 257 (1986). If this evidence has been presented, there is a genuine issue of fact that requires a trial. *Id.* The court, when making this determination, must believe the evidence of the nonmoving party, and draw all justifiable inferences in his or her favor. *Id.* 477 U.S. at 255; *Rollins v. TechSouth, Inc.*, 833 F.2d 1525, 1529 (11th Cir. 1987).

An issue is not genuine, however, if it is unsupported by evidence or if it is created by evidence that is "merely colorable" or is "not significantly probative." *Anderson*, 477 U.S. at 249-50. Similarly, a fact is not material unless it is identified by the controlling substantive law as an essential element of the nonmoving party's case. *Id.* at 248. Thus, to create a genuine issue of material fact for trial, parties opposing summary judgment must come forward with specific evidence to establish every element essential to their case with respect to which: (1) they have the burden of proof; and (2) the summary judgment movant has made a plausible showing of the absence of evidence to establish that element. *Celotex*, 477 U.S. at 323.

Although patent infringement cases typically involve complex questions of fact precluding summary adjudication, summary judgment may properly be granted if no genuine issues of material fact remains for trial. Indeed:

> [m]any, if not most suits for patent infringement give rise to numerous and complex fact issues, rendering those suits inappropriate for summary disposition. When no issue of material fact is present, however, courts should not hesitate to avoid an unnecessary trial by proceeding under Fed. R. Civ. P. 56 without regard to the particular type of suit involved.

Cooper v. Ford Motor Co., 748 F.2d 677, 679 [223 USPQ 1286] (Fed. Cir. 1984) (quoting *Chore-Time Equip., Inc. v. Cumberland Corp.*, 713 F.2d 774, 778-79 [218 USPQ 673] (Fed. Cir. 1983)).

Facts

With this standard in mind, the court finds the following pertinent facts solely for the

purpose of resolving Glaxo's summary judgment motion.

In June, 1989, at the Fifth International Conference On AIDS, scientists working for BioChem disclosed their discovery of a novel class of synthetic nucleoside compounds that exhibit significant activity against HIV, the virus that causes AIDS. One of the chemical compounds that BioChem disclosed at that conference was "β-2', 3'-dideoxy-3'-thiacytidine," also known as BCH-189.

BCH-189 is a chemical compound generally known as a "racemate" or a "racemic mixture." A racemate or racemic mixture is an equal-parts (50/50) mixture of two separate enantiomers, namely a (-) enantiomer (sometimes referred to as the "left-handed" enantiomer), and a (+) enantiomer (sometimes referred to as the "right-handed" enantiomer). Enantiomers are compounds that have identical molecular and chemical formulas but differ in the way their atoms are arranged three-dimensionally in space. Enantiomers are also known as optical isomers. In other words, BCH-189, a racemic mixture, consists of equal parts (-) and (+) enantiomers. And the (-) and (+) enantiomers that make up BCH-189 are non-superimposable mirror images of each other, similar to a person's left and right hands.

Although this court has not yet been called upon to construe Emory's '116 patent, all parties concede, for the purposes of the instant motion, that Emory's '116 patent claims two compounds: (1) 3TC, which is the (-) enantiomer of BCH-189; and (2) a mixture of 3TC and the (+) enantiomer that is "enriched" in one or the other enantiomer.

In February, 1989 shortly before BioChem disclosed to the world at the Fifth International Conference on AIDS that its scientists had discovered BCH-189, BioChem filed a patent application on that chemical compound. That application later resulted in the issuance of United States Patent No. 5,047,407, which has been referred to during this case by all of the parties as the '407 patent.

All parties concede that BioChem's '407 patent discloses the use of "a broad class of oxathiolane nucleosides to treat HIV infections, including BCH-189." Indeed, Formula XI of the '407 patent illustrates BCH-189, Example 7(b) of the '407 patent discusses the production of BCH-189, and Claim 10 of the '407 patent claims both BCH-189 and "the geometric and optical isomers [enantiomers] thereof, and mixtures of those isomers [.]" The '407 patent, however, does not disclose any method, or contain any information on how, to obtain, or "resolve," the separate enantiomers of BCH-189.

In February of 1990, just under a year after BioChem's scientists had disclosed BCH-189, Emory filed a patent application of its own ("the February application"). Emory's February application later led to the issuance of both the '116 patent, the patent at issue in this case, and a patent referred to by the parties as the '466 patent. In the February application, Emory disclosed that its invention had three distinct aims: (1) to provide an efficient process for making the BCH-189 mixture (which Emory contends was needed because the process of obtaining BCH-189 published by BioChem was inefficient); (2) to provide a process that allowed the preparation of analogous compounds; and (3) to provide a process for obtaining the enantiomers of BCH-189 in separate and enriched form. The '466 patent not at issue in this case was granted with claims to the efficient process of obtaining BCH-189. The '116 patent at issue in this case was granted with claims to the process and method for obtaining the enantiomers of BCH-189 in separate and enriched form.

Three months after Emory filed the February application, in May of 1990, Glaxo Wellcome plc filed a patent application in the United Kingdom, naming several Glaxo scientists as inventors. That application specifically claimed the (-) enantiomer of BCH-189, which, as described above, later became known as 3TC, and set forth detailed information about that enantiomer, including its biological activity and its unexpectedly lower comparative cytotoxicity. Glaxo's May 1990 application was later assigned to BioChem. In May of 1991, the application was filed as an International Application. It was published in November of 1991. In Glaxo's May 1990 application, the Glaxo scientists state, among other things, "[w]e have now found that, surprisingly, enantiomers of [BCH-189] are equipotent against HIV but that one of the enantiomers (the (-) enantiomer) has considerably lower cytotoxicity than the other enantiomer."

Just over two years after the International Application was published, on February 10, 1993, Emory filed a "divisional application" based upon its February 1990 patent application. Because Emory's divisional application was based upon the February 1990 patent application, the divisional application which Emory filed in 1993 had the same specification as the application that Emory filed in February 1990. On that same day, Emory also filed a "Preliminary Amendment" in which Emory submitted a specific claim to the (-) enantiomer of BCH-189, or

in other words, to 3TC. Emory's claims were eventually allowed, and the '116 patent, the patent in question in this case, issued on July 23, 1996. Emory filed the instant patent infringement suit that same day.

Discussion

Glaxo moves the court to declare Emory's '116 patent invalid as a matter of law. Glaxo bases its motion on two independent grounds. First, Glaxo argues that the '116 patent fails to provide an adequate written description of the invention as required by 35 U.S.C. § 112. Thus, Glaxo argues, the '116 patent fails to provide the necessary descriptive information to show that Emory was in possession of 3TC at the time it filed its February 1990 patent application. Second, Glaxo argues that, under 35 U.S.C. § 103, the '116 patent is obvious over BioChem's prior disclosure of the racemate BCH-189. This proposition is true, Glaxo argues, because in the '116 patent the inventors fail to recognize the unexpected properties of 3TC that make a claim to 3TC patentable over BioChem's prior disclosure of BCH-189. BioChem joins Glaxo's motion and has submitted a brief supporting Glaxo's position. BioChem's brief, however, focuses primarily upon Glaxo's argument that the '116 patent does not contain an adequate written description of the invention.

Emory responds to Glaxo's first argument by stating that the question of whether the '116 patent's specification provides an adequate written description of the claim is a question of fact upon which it has raised a triable issue. Specifically, Emory contends that it has raised a triable issue on this question by submitting expert testimony that the specification contained in the '116 patent conveys with reasonable clarity to those skilled in the art, that, as of February, 1990, the date upon which Emory filed its initial application, Emory was in possession of the invention 3TC. With regard to Glaxo's second argument, Emory concedes that describing an enantiomer's unexpected properties is one way to make the enantiomer non-obvious over the disclosure of that enantiomer's racemate, but Emory argues that it is not the only way. Specifically, Emory contends that it can show that 3TC was not obvious in light of BioChem's disclosure of BCH-189 because at the time Emory filed its patent application there was no known or obvious way to "resolve" BCH-189 into either of its separate enantiomers, including the (-) enantiomer, 3TC.

The court will address each of Glaxo's arguments in turn.

1. *Adequate written description*

The adequate written description requirement of 35 U.S.C. § 112, ¶ 1, provides that a patent's specification:

> shall contain a *written description of the invention*, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(emphasis added). This requirement, which is separate and distinct from the patent law's enablement and best mode requirements, "serves to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him [.]" *In re Alton*, 76 F.3d 1168, 1172 [37 USPQ2d 1578] (Fed. Cir. 1996) (internal quotation and citation omitted).

To meet the requirement of § 112, the patent application need not utilize any particular form of disclosure. Instead, "the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." *Alton*, 76 F.3d at 1172. Stated in different terms, the written description requirement requires the patent applicant to "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*." *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 [19 USPQ2d 1111] (Fed. Cir. 1991).

[2] Although both Glaxo and BioChem argue that the issue of whether Emory's '116 patent complies with the § 112 can be decided as a matter of law, it is now well settled that the issue of whether, under § 112, a patent specification adequately describes the subject matter claimed is a question of fact. *Id.* at 1563. Indeed, as the Federal Circuit has recently reiterated, "precisely how close the original description must come to comply with the description requirement of section 112 must be determined on a case-by-case basis." *Alton*, 76 F.3d at 1172 (quoting *Eiselstein v. Frank*, 52 F.3d 1035, 1039 [34 USPQ2d 1467] (Fed. Cir. 995).

Despite this well settled precedent, Glaxo argues in its brief that:

> [g]iven the complete absence in the '116 Patent specification of any description of the properties of the (-) -enantiomer of BCH-189 and the lack of any specific recognition that the (-) -enantiomer is biologically active, it is evident that the '116

> Patent does not contain a written description of the (-) -enantiomer as a matter of law. No fact development is needed and no expert or other testimony would be proper on this point.

(Glaxo mem., p. 5) Similarly, BioChem contends that "no expert testimony, evidence or lawyering can retroactively insert the required description of the (-) optical isomer of BCH-189 in [Emory's February 1990] application." (BioChem mem., p. 8).

Specifically, Glaxo argues that the specification in Emory's '116 patent is inadequate because it: (1) fails to disclose any anti-HIV activity data or any other biological activity data specific to the (-) enantiomer of BCH-189; (2) fails to provide any cytotoxicity data specific to the (-) enantiomer of BCH-189; (3) fails to disclose that the (-) enantiomer of BCH-189 is biologically active; (4) fails to state that the invention claimed is the (-) enantiomer of BCH-189; (5) incorrectly states that one of the enantiomers of BCH-189 is inactive, but fails to disclose which one; (6) implies that the (-) enantiomer of BCH-189 is as likely as the (+) enantiomer of BCH-189 to be inactive; and (7) implicitly suggests the incorrect conclusion that the (-) enantiomer of BCH-189 is inactive. Therefore, Glaxo argues, because the '116 patent's specification contains no information whatsoever on the properties of the (-) enantiomer of BCH-189, the named Emory inventors cannot possibly establish that, when the February 1990 patent application was filed, they were in possession of 3TC.

Emory responds that there are a number of statements in the February 1990 patent application that disclose that Emory both had invented a process for resolving the separated or enriched enantiomers of BCH-189 and had invented those compounds *per se*. More particularly, Emory points to the following statements that are found in the February 1990 application:

> The present invention relates to a method of preparing BCH-189 and various analogs of BCH-189 from inexpensive precursors with the option of introducing functionality as needed. This synthetic route allows the stereoselective preparation of the biologically active isomer of these compounds, β-BCH-189 and related compounds. Furthermore, the stereochemistry at the nucleoside 4' position can be controlled to produce enantiomerically-enriched β-BCH-189 and its analogs.
>
> * * * * *
>
> More particularly, the invention relates to the selective synthesis of the β-isomer of BCH-189 and related compounds as well as the selective synthesis of enantiomerically-enriched BCH-189 and related compounds.
>
> * * * * *
>
> This synthetic route allows the stereoselective preparation of the biologically active isomer of these compounds, β-BCH-189 and related compounds. Furthermore, the stereochemistry at the nucleoside 4' position can be controlled to produce enantiomerically-enriched β-BCH-189 and its analogs.
>
> * * * * *
>
> Accordingly, one of the objectives of this invention is to provide an efficient method for preparing the β-isomer of BCH-189 and analogs of BCH-189 in high yields. Furthermore, it is an objective of this invention to provide a synthetic method to produce only one optical isomer, rather than a racemic mixture, of BCH-189 and analogs of BCH-189. A further object of this invention is to provide a synthetic route to produce β-BCH-89 that is enantiomerically-enriched.
>
> * * * * *
>
> This procedure can be tailored to produce BCH-189 or BCH-189 analogs that are enantiomerically-enriched at the 4' position by selecting an appropriate R protecting group to allow stereoselective enzymatic hydrolysis of *3* by an enzyme such as pig liver esterase, porcine pancreatic lipase, or subtilisin or other enzymes that hydrolyze *3* in a stereoselective fashion.

While Emory concedes that the February 1990 application does not specifically refer to the "(-)" label, it argues that every ordinarily skilled chemist knew, at that time, that in every pair of enantiomers one is (+) and the other is (-). Therefore, Emory contends, simply omitting the (-) label does not make its '116 patent specification inadequate.

On the contrary, Emory continues, the statements listed above convey to an ordinarily skilled chemist that the Emory inventors were in possession of the (-) enantiomer of BCH-189. Emory supports this contention by submitting the expert affidavit of Alexander M. Klibanov ("Klibanov"), a professor of chemistry at the Massachusetts Institute of Technology ("MIT"), whose research focuses upon the use of enzymes to synthesize optically active compounds. Klibanov states he is familiar with stereochemistry and, more particularly, the state of the art in that field as of February 1990. Klibanov further opines that based upon the disclosure listed above the clear objective of Emory's February 1990 patent application "is to provide each of the two enantiomers in separate

or enriched form." (Klibanov Aff., ¶ 10) In addition, Klibanov states that the disclosures listed above confirm that "the Emory application provides each of the two enantiomers [of BCH-189], one of them necessarily being the (-) one." (Klibanov Aff., ¶ 11).

Based upon a review of the information that has been submitted to it, including the evidence described above, the court finds that genuine issues of material fact remain on the question of whether the specification of the '116 patent contains an adequate written description of the claimed invention 3TC. Accordingly, to the extent that Glaxo's motion seeks summary judgment declaring Emory's '116 patent invalid as a matter of law on grounds that it fails to contain an adequate written description under 35 U.S.C. § 112, it is DENIED.

2. *"Obviousness" under 35 U.S.C. § 103*

Under 35 U.S.C. § 103:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Whether the invention claimed in a patent is obvious within the meaning of 35 U.S.C. § 103 is considered ultimately to be a legal conclusion. *See Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1270 [20 USPQ2d 1746] (Fed. Cir. 1991). Nevertheless, the Supreme Court has instructed courts to make three factual inquires and to weigh other "secondary considerations" before reaching the ultimate determination of law. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 [148 USPQ 459] (1966). Indeed, before it can determine that an invention is obvious, a court must examine facts relating to: (1) the scope and content of the prior art; (2) differences between the prior art and the claims at issue; and (3) the level of ordinary skill in the pertinent art. *Id.*; *see, also, Cooper v. Ford Motor Co.*, 748 F.2d 677, 679 [223 USPQ 1286] (Fed. Cir. 1984); *Continental Can*, 948 F.2d at 1270. Courts may also consider other relevant factual considerations such as commercial success, long-felt but unsolved need, and the failure of others. *Graham*, 383 U.S. at 17-18. Summary judgment on the basis of obviousness is appropriate only when there is no genuine issue as to any of these material facts. *Continental Can*, 948 F.2d at 1269-73; *Cooper*, 748 F.2d at 679.

To support its argument that the subject matter of Emory's '116 patent (the (-) enantiomer of BCH-189) was obvious at the time Emory filed the February 1990 patent application, Glaxo cites several cases standing for the general proposition that an enantiomer, or an optical isomer, is not patentable over its known racemic mixture unless the enantiomer sought to be patented possessed unexpected beneficial properties not possessed by the racemic mixture itself. *See, Brenner v. Ladd*, 247 F.Supp. 51, 56 [147 USPQ 87] (D.D.C. 1965) (in the absence of unexpected or unobvious beneficial properties, an optical isomer is unpatentable over either the other optical isomer or the racemic mixture itself); *In re May*, 574 F.2d 1082 [197 USPQ 601] (CCPA 1960) (optical isomer was *prima facie* obvious over racemate, but found patentable where unexpected beneficial properties shown). Thus, relying on the prior art of BioChem's '407 patent which discloses the racemic mixture BCH-189, Glaxo argues that the enantiomers of BCH-189 were obvious and unpatentable at the time Emory filed its February 1990 application.

[3] Although the court agrees with Glaxo's general proposition that disclosure of the racemate or racemic mixture makes *prima facie* obvious the separate enantiomers of that racemate, it has long been held that "if the prior art of record fails to disclose or render obvious a method for making a claimed compound, at the time the invention was made, it may not be legally concluded that the compound itself is in the possession of the public." *In re Hoeksema*, 399 F.2d 269, 274 [158 USPQ 596] (CCPA 1968). According to Emory's expert chemist, Klibanov BioChem's '407 patent, which Glaxo cites as the prior art that makes the subject matter of Emory's '116 patent obvious, would not have enabled a person of ordinary skill in the art as of February 1990 to obtain the (-) and (+) enantiomers of BCH-189 in separate or enriched form. (Klibanov Aff., ¶ 17). Indeed, according to Klibanov, "[t]o obtain the enantiomers [of BCH-189] in separate or enriched form, one must have a procedure for accomplishing that. The BioChem '407 has no disclosure, and not even a suggestion, of how to do it." (Klibanov Aff., ¶ 17). Based upon this evidence, the court finds that a question remains as to whether the (-) enantiomer of BCH-189 was in possession of the public at the time Emory filed its February 1990 application. Accordingly, the court cannot, at this time, legally conclude that the subject matter of Emory's '116 patent was obvious over BioChem's prior disclosure of BCH-189. Glaxo's motion for summary

judgment, therefore, to the extent that it seeks judgment declaring Emory's '116 patent obvious as a matter of law, is DENIED.

SUMMARY

Defendant Glaxo Wellcome, Inc.'s motion for summary judgment [docket no. 78] is DENIED.

SO ORDERED.

U.S. Patent and Trademark Office
Trademark Trial and Appeal Board

Salacuse v. Ginger Spirits Inc.

Cancellation No. 24,813

Decided September 12, 1997
(Unpublished)

TRADEMARKS AND UNFAIR TRADE PRACTICES

1. Practice and procedure in Patent and Trademark Office — Interpartes proceedings — Opposition and cancellation — In general (§325.0305.01)

Cancellation petitioner, for purposes of determining priority, is entitled to rely on filing date of his intent-to-use applications as constructive date of first use of mark on goods identified therein, and is entitled to assert constructive use date offensively in support of claim under Lanham Act's Section 2(d), 15 USC 1052(d), but petitioner's pleaded applications are not immune to challenge in cancellation proceeding.

2. Acquisition, assignment, and maintenance of marks — Acquisition through use — Priority of use (§305.0503)

Practice and procedure in Patent and Trademark Office — Interpartes proceedings — Opposition and cancellation — In general (§325.0305.01)

Cancellation respondent may challenge validity of petitioner's pleaded intent-to-use applications, which are sole basis for petitioner's claim of constructive use priority under Lanham Act's Section 2(d), 15 USC 1052(d), since petitioner's priority is contingent upon maturing of his prior-filed applications into registrations, not merely upon pendency of those applications, and since it is not inequitable to require petitioner to go beyond mere pendency of applications and establish his entitlement to registrations upon which priority claim is based.

3. Acquisition, assignment, and maintenance of marks — Acquisition through use — Priority of use (§305.0503)

Practice and procedure in Patent and Trademark Office — Interpartes proceedings — Opposition and cancellation — In general (§325.0305.01)

Finding that cancellation petitioner's intent-to-use applications are invalid for lack of requisite bona fide intention to use applied-for mark on goods identified in applications would not be basis for any official action by Trademark Trial and Appeal Board with respect to petitioner's applications, since board lacks jurisdiction to declare petitioner's applications void for lack of bona fide intention to use; however, such finding would constitute sufficient defense to petitioner's priority claim against respondent's registration in cancellation proceeding.

4. Acquisition, assignment, and maintenance of marks — Acquisition through use — Priority of use (§305.0503)

Practice and procedure in Patent and Trademark Office — Interpartes proceedings — Opposition and cancellation — In general (§325.0305.01)

Mere pendency of cancellation petitioner's prior-filed intent-to-use applications is not dispositive of priority issue in cancellation proceeding, and Trademark Trial and Appeal Board can require petitioner, who has burden of proof on that issue, to go beyond mere fact that he filed those applications, and establish entitlement to registrations sought in those applications.

5. Acquisition, assignment, and maintenance of marks — Acquisition through use — Priority of use (§305.0503)

Registration and its effects — Federal registration — Procedure, form and content — Intent to use (§315.0303.12)

Cancellation respondent has submitted sufficient evidence to establish existence of genuine issue of material fact as to whether petitioner, as of filing date of his pleaded intent-to-use applications, possessed requisite bona fide intent to use applied-for mark on identified goods, since evidence shows that, in addition to pleaded applications to register mark "South Beach" for food and beverage products, petitioner has filed numerous other intent-to-use applications to register mark for wide variety of other goods, including luggage, furniture, and motor vehicles, as well as additional applications to